

only for the suggestion CMS received first, if the suggestion or overlapping part of the suggestion are identical, and CMS has adopted that part. If the suggestions are not identical, CMS will consider rewarding the suggestion received first, if it is feasible and CMS is able to adopt and implement the suggestion. If the first suggestion cannot be implemented, CMS may consider rewarding the suggestion received next, even if it is similar, provided CMS can adopt and implement the suggestion.

(2) *Issuance of reward payment.* After the reward payment amount is determined, as described in paragraph (g) of this section, CMS mails payment to the suggester (or to the legal representatives referenced in paragraph (k) of this section) only after the suggestion has been in operation for 1 year.

(i) *Group suggestions.* When CMS deems that a reward payment is appropriate for a suggestion submitted by a group of individuals, CMS pays an equal share of the reward to each of the individuals identified in the group. If an organization such as a corporation, partnership, or professional association submits a suggestion, CMS makes a single reward payment to that organization.

(j) *Change in name or address.* It is the suggester's responsibility to notify CMS of any change of address or other relevant information. If the suggester fails to update CMS on any change in this information, and the reward payment mailed to the suggester is returned to CMS, the suggester must claim the reward payment by contacting CMS within 1 year from the date CMS first mailed the reward payment to the suggester. CMS does not pay interest on rewards that, for any reason, are delayed or are not immediately claimed.

(k) *Incapacitated or deceased suggester.* If the suggester is incapacitated or has died, an executor, administrator, or other legal representative may claim the reward on behalf of the suggester or the suggester's estate. The claimant must submit certified copies of the letters testamentary, letters of administration, or other similar evidence to CMS showing his or her authority to claim the reward. The claim must be

filed within 1 year from the date on which CMS first attempted to pay the reward to the individual who submitted the suggestion.

(1) *Maintenance of records*—(1) CMS retains records related to the administration of the suggestion program in accordance with 36 CFR part 1228 (the regulations for the National Archives and Records Administration).

(2) CMS does not disclose information submitted under the suggestion program, except as required by law.

[64 FR 66401, Nov. 26, 1999]

## PART 421—INTERMEDIARIES AND CARRIERS

### Subpart A—Scope, Definitions, and General Provisions

Sec.

421.1 Basis and scope.

421.3 Definitions.

421.5 General provisions.

### Subpart B—Intermediaries

421.100 Intermediary functions.

421.103 Options available to providers and CMS.

421.104 Nominations for intermediary.

421.105 Notification of action on nomination.

421.106 Change to another intermediary or to direct payment.

421.110 Requirements for approval of an agreement.

421.112 Considerations relating to the effective and efficient administration of the program.

421.114 Assignment and reassignment of providers by CMS.

421.116 Designation of national or regional intermediaries.

421.117 Designation of regional and alternative designated regional intermediaries for home health agencies and hospices.

421.118 Awarding of experimental contracts.

421.120 Performance criteria.

421.122 Performance standards.

421.124 Intermediary's failure to perform efficiently and effectively.

421.126 Termination of agreements.

421.128 Intermediary's opportunity for hearing and right to judicial review.

### Subpart C—Carriers

421.200 Carrier functions.

421.201 Performance criteria and standards.

421.202 Requirements and conditions.

## § 421.1

421.203 Carrier's failure to perform efficiently and effectively.

421.205 Termination by the Secretary.

421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.

421.212 Railroad Retirement Board contracts.

421.214 Advance payments to suppliers furnishing items or services under Part B.

AUTHORITY: Secs. 1102 and 1871 of the Social Security Act (42 U.S.C. 1302 and 1395hh).

SOURCE: 45 FR 42179, June 23, 1980, unless otherwise noted.

### Subpart A—Scope, Definitions, and General Provisions

#### § 421.1 Basis and scope.

(a) This part is based on the indicated provisions of the following sections of the Act:

1124—Requirements for disclosure of certain information.

1816 and 1842—Use of organizations and agencies in making Medicare payments to providers and suppliers of services.

(b) Section 421.118 is also based on 42 U.S.C.1395b-1(a)(1)(F), which authorizes demonstration projects involving intermediary agreements and carrier contracts.

(c) The provisions of this part apply to agreements with Part A (Hospital Insurance) intermediaries and contracts with Part B (Supplementary Medical Insurance) carriers. They also state that CMS may perform certain functions directly or by contract. They specify criteria and standards to be used in selecting intermediaries and evaluating their performance, in assigning or reassigning a provider or providers to particular intermediaries, and in designating regional or national intermediaries for certain classes of providers. The provisions set forth the instances where there is the opportunity for a hearing for intermediaries and carriers affected by certain adverse actions. In some circumstances, the adversely affected intermediaries may request a judicial review of hearings decisions on—

(1) Assignment or reassignment of a provider or providers; or

## 42 CFR Ch. IV (10-1-03 Edition)

(2) Designation of an intermediary or intermediaries to serve a class of providers.

[49 FR 3659, Jan. 30, 1984, as amended at 60 FR 50442, Sept. 29, 1995]

#### § 421.3 Definitions.

*Intermediary* means an entity that has a contract with CMS to determine and make Medicare payments for Part A or Part B benefits payable on a cost basis (or under the Prospective Payment System for hospitals) and to perform other related functions. For purposes of designating regional or alternative regional intermediaries for home health agencies and of designating intermediaries for hospices under § 421.117 as well as for applying the performance criteria in § 421.120 and the performance standards in § 421.122 and any adverse action resulting from such application, the term intermediary also means a Blue Cross Plan which has entered into a subcontract approved by CMS with the Blue Cross and Blue Shield Association to perform intermediary functions.

[59 FR 681, Jan. 6, 1994]

#### § 421.5 General provisions.

(a) *Competitive bidding not required for carriers.* CMS may enter into contracts with carriers, or with intermediaries to act as carriers in certain circumstances, without regard to section 3709 of the U.S. Revised Statutes or any other provision of law that requires competitive bidding.

(b) *Indemnification of intermediaries and carriers.* Intermediaries and carriers act on behalf of CMS in carrying out certain administrative responsibilities that the law imposes. Accordingly, their agreements and contracts contain clauses providing for indemnification with respect to actions taken on behalf of CMS and CMS is the real party of interest in any litigation involving the administration of the program.

(c) *Use of intermediaries to perform carrier functions.* CMS may contract with an intermediary to perform carrier functions with respect to services for which Part B payment is made to a provider.

(d) *Nonrenewal of agreement or contract.* Notwithstanding any of the provisions of this part, CMS has the authority not to renew an agreement or contract when its term expires.

(e) *Intermediary availability in an area.* For more effective and efficient administration of the program, CMS retains the right to expand or diminish the geographical area in which an intermediary is available to serve providers.

(f) *Provision for automatic renewal.* Agreements and contracts under this part may contain automatic renewal clauses for continuation from term to term unless either party gives notice, within timeframes specified in the agreement or contract, of its intention not to renew.

[45 FR 42179, June 23, 1980, as amended at 54 FR 4026, Jan. 27, 1989]

## Subpart B—Intermediaries

### § 421.100 Intermediary functions.

An agreement between CMS and an intermediary specifies the functions to be performed by the intermediary, which must include, but are not necessarily limited to, the following:

(a) *Coverage.* (1) The intermediary ensures that it makes payments only for services that are:

(i) Furnished to Medicare beneficiaries;

(ii) Covered under Medicare; and

(iii) In accordance with QIO determinations when they are services for which the QIO has assumed review responsibility under its contract with CMS.

(2) The intermediary takes appropriate action to reject or adjust the claim if—

(i) The intermediary or the QIO determines that the services furnished or proposed to be furnished were not reasonable, not medically necessary, or not furnished in the most appropriate setting; or

(ii) The intermediary determines that the claim does not properly reflect the kind and amount of services furnished.

(b) *Fiscal management.* The intermediary must receive, disburse, and account for funds in making Medicare payments.

(c) *Provider audits.* The intermediary must audit the records of providers of services as necessary to assure proper payments.

(d) *Utilization patterns.* The intermediary must assist providers to—

(1) Develop procedures relating to utilization practices;

(2) Make studies of the effectiveness of those procedures and recommend methods to improve them;

(3) Evaluate the results of utilization review activity; and

(4) Assist in the application of safeguards against unnecessary utilization of services.

(e) *Resolution of cost report disputes.* The intermediary must establish and maintain procedures approved by CMS to consider and resolve any disputes that may result from provider dissatisfaction with an intermediary's determinations concerning provider cost reports.

(f) *Reconsideration of determinations.* The intermediary must establish and maintain procedures approved by CMS for the reconsideration of its determinations to deny payments to an individual or to the provider that furnished services to the individual. The QIO performs reconsideration of cases in which it made a determination subject to reconsideration.

(g) *Information and reports.* The intermediary must furnish to CMS any information and reports that CMS requests in order to carry out its responsibilities in the administration of the Medicare program.

(h) *Other terms and conditions.* The intermediary must comply with all applicable laws and regulations and with any other terms and conditions included in its agreement.

(i) *Dual intermediary responsibilities.* With respect to the responsibility for service to provider-based HHAs and provider-based hospices, where the HHA or hospice and its parent provider will be served by different intermediaries under § 421.117 of this part, the designated regional intermediary will process bills, make coverage determinations and make payments to the HHAs and hospices. The intermediary serving the parent provider will perform all fiscal functions, including audits and settlement of the Medicare

### § 421.103

cost reports and the HHA and hospice supplement worksheets.

[45 FR 42179, June 23, 1980, as amended at 48 FR 7178, Feb. 18, 1983; 49 FR 3659, Jan. 30, 1984; 51 FR 43198, Dec. 1, 1986; 53 FR 17944, May 19, 1988; 54 FR 4026, Jan. 27, 1989]

#### § 421.103 Options available to providers and CMS.

(a) Except for hospices (which are covered under § 421.117), a provider may elect to receive payment for covered services furnished to Medicare beneficiaries—

(1) Directly from CMS (subject to the provisions of paragraph (b) of this section); or

(2) Through an intermediary, when both CMS and the intermediary consent.

(b) Whenever CMS determines it appropriate, it may contract with any organization (including an intermediary with which CMS has previously entered into an agreement under § 421.105 and § 421.110 or designated as a regional or alternative regional intermediary under § 421.117) for the purposes of making payments to any provider that does not elect to receive payment from an intermediary.

[49 FR 3659, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984]

#### § 421.104 Nominations for intermediary.

(a) *Nomination by groups or associations of providers.* (1) An association of providers, except for hospices, may nominate an organization or agency to serve as intermediary for its members.

(2) The nomination is not binding on any member of the association if it notifies CMS of its nonconcurrence with the nomination.

(3) The nomination must be made in writing, to CMS, and must—

(i) Identify the proposed intermediary by giving the complete name and address;

(ii) Include, or furnish as an attachment, the name, address, and bed capacity (or patient care capacity in the case of home health agencies) of each member of the association;

(iii) List the members that have concurred in the nomination of the proposed intermediary; and

### 42 CFR Ch. IV (10–1–03 Edition)

(iv) Be signed by an authorized representative of the association.

(b) *Action by nonmembers or non-concurring members.* Providers that non-concur in their association's nomination, or are not members of an association, may—

(1) Form a group of 2 or more providers for the specific purpose of nominating an intermediary, in accordance with provisions of paragraph (a) of this section;

(2) Elect to receive payments from a fiscal intermediary with which CMS already has an agreement, if CMS and the intermediary agree to it (see § 421.106); or

(3) Elect to receive payment from CMS as provided in § 421.103.

(c) CMS is not required to enter into an agreement with a proposed intermediary solely because it has been nominated.

[45 FR 42179, June 23, 1980, as amended at 48 FR 56035, Dec. 16, 1983; 49 FR 3659, Jan. 30, 1984]

#### § 421.105 Notification of action on nomination.

(a) CMS will send, to each member of a nominating association or group, written notice of a decision to enter into or not enter into an agreement with the nominated organization or agency.

(b) Any member of a group or association having more than one nominated intermediary approved by CMS to act on its behalf must withdraw its nomination from all but one or exercise the option provided in § 421.103(a), subject to § 421.103(b), to receive payment directly from CMS.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

#### § 421.106 Change to another intermediary or to direct payment.

(a) Any provider may request a change of intermediary, or except for a hospice, that it be paid directly by CMS, by—

(1) Giving CMS written notice of its desire at least 120 days before the end of its current fiscal year; and

(2) Concurrently giving written notice to its intermediary.

(b) If CMS finds the change is consistent with effective and efficient administration of the program and approves the request under paragraph (a) of this section, it will notify the provider, the outgoing intermediary, and the newly-elected intermediary (if any) that the change will be effective on the first day following the close of the fiscal year in which the request was filed.

[45 FR 42179, June 23, 1980, as amended at 49 FR 56036, Dec. 16, 1983; 49 FR 3660, Jan. 30, 1984]

**§ 421.110 Requirements for approval of an agreement.**

Before entering into or renewing an intermediary agreement, CMS will—

(a) Determine that to do so is consistent with the effective and efficient administration of the Medicare program;

(b) Review the performance of the intermediary as measured by the criteria (§ 421.120) and standards (§ 421.122); and

(c) Determine that the intermediary or prospective intermediary—

(1) Is willing and able to assist providers in the application of safeguards against unnecessary utilization of services;

(2) Meets all solvency and financial responsibility requirements imposed by the statutes and regulatory authorities of the State or States in which it, or any subcontractor performing some or all of its functions, would serve;

(3) Has the overall resources and experience to administer its responsibilities under the Medicare program and has an existing operational, statistical, and recordkeeping capacity to carry out the additional program responsibilities it proposes to assume. CMS will presume that an intermediary or prospective intermediary meets this requirement if it has at least 5 years experience in paying for or reimbursing the cost of health services;

(4) Will serve a sufficient number of providers to permit a finding of effective and efficient administration. Under this criterion no intermediary or prospective intermediary shall be found to be not efficient or effective solely on the grounds that it serves only providers located in a single State;

(5) Has acted in good faith to achieve effective cooperation with the providers it will service and with the physicians and medical societies in the area;

(6) Has established a record of integrity and satisfactory service to the public; and

(7) Has an affirmative equal employment opportunity program that complies with the fair employment provisions of the Civil Rights Act of 1964 and Executive Order 11246, as amended.

**§ 421.112 Considerations relating to the effective and efficient administration of the program.**

(a) In order to accomplish the most effective and efficient administration of the Medicare program, determinations may be made by the Secretary with respect to the termination of an intermediary agreement, or by CMS with respect to the—

(1) Renewal of an intermediary agreement (§ 421.110);

(2) Assignment or reassignment of providers to an intermediary (§ 421.114); or

(3) Designation of a regional or national intermediary to serve a class of providers (§ 421.116).

(b) When taking the actions listed in paragraph (a), the Secretary or CMS will consider the performance of the individual intermediary in its Medicare operations using the factors contained in the performance criteria (§ 421.120) and performance standards (§ 421.122).

(c) In addition, when taking the actions listed in paragraph (a) of this section, the Secretary or CMS may consider factors relating to—

(1) Consistency in the administration of program policy;

(2) Development of intermediary expertise in difficult areas of program administration;

(3) Individual capacity of available intermediaries to serve providers as it is affected by such considerations as—

(i) Program emphasis on the number or type of providers to be served; or

(ii) Changes in data processing technology;

(4) Overdependence of the program on the capacity of an intermediary to an extent that services could be interrupted;

#### § 421.114

- (5) Economy in the delivery of intermediary services;
- (6) Timeliness in the delivery of intermediary services;
- (7) Duplication in the availability of intermediaries;
- (8) Conflict of interest between an intermediary and provider; and
- (9) Any additional pertinent factors.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994]

#### § 421.114 Assignment and reassignment of providers by CMS.

CMS may assign or reassign any provider to any intermediary if it determines that the assignment or reassignment will result in a more effective and efficient administration of the Medicare program. Before making this determination CMS will consider—

- (a) The preferences of the provider;
- (b) The availability of an intermediary as specified in § 421.5(e); and
- (c) Intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

#### § 421.116 Designation of national or regional intermediaries.

(a) After considering intermediary performance measured against the criteria and standards specified in §§ 421.120 and 421.122, CMS may designate a particular intermediary to serve a class of providers nationwide or in any geographic area it defines. CMS may make this designation if it determines that the designation will result in a greater degree of effectiveness and efficiency in the administration of the Medicare program than could be achieved by an assignment of providers to an intermediary preferred by the providers.

(b) No designation may be made until the affected providers and intermediaries are given an explanation and the intermediaries are advised of their right to a hearing and judicial review as specified in § 421.128. This provision does not apply to experimental contracts awarded under § 421.118.

(c) To designate an intermediary, CMS may establish classes of providers on the basis of—

#### 42 CFR Ch. IV (10–1–03 Edition)

- (1) The type of provider, for example, hospital, skilled nursing facility, home health agency; or
- (2) Common characteristics.

[45 FR 42179, June 23, 1980, as amended at 49 FR 3660, Jan. 30, 1984]

#### § 421.117 Designation of regional and alternative designated regional intermediaries for home health agencies and hospices.

(a) This section is based on section 1816(e)(4) of the Social Security Act, which requires the Secretary to designate regional intermediaries for home health agencies (HHAs) other than hospital-based HHAs but permits him or her to designate regional intermediaries for hospital-based HHAs only if the designation meets promulgated criteria concerning administrative efficiency and effectiveness; on section 1816(e)(5) of the Social Security Act, which requires the Secretary to designate intermediaries for hospices; and on section 1874 of the Act, which permits CMS to contract with any organization for the purpose of making payments to any provider that elects to receive payment directly from CMS.

(b) CMS applies the following criteria to determine whether the assignment of hospital-based HHAs to designated regional intermediaries will result in the more effective and efficient administration of the Medicare program:

- (1) Uniform interpretation of Medicare rules;
- (2) Expertise in bill processing;
- (3) Control of administrative costs;
- (4) Ease of communication of program policy and issues to affected providers;
- (5) Ease of data collection;
- (6) Ease of CMS's monitoring of intermediary performance; and
- (7) Other criteria as the Secretary believes to be pertinent.

(c) Except as provided in paragraphs (e), (f), and (g) of this section, an HHA must receive payment through a regional intermediary designated by CMS.

(d) Except as provided in paragraphs (f) through (h) of this section, a hospice must receive payment for covered services furnished to Medicare beneficiaries through an intermediary designated by CMS.

(e) An HHA chain not desiring to receive payment from designated regional intermediaries may request service by one lead intermediary with the assistance of a local designated regional intermediary. Alternatively, the chain may request to be serviced by a single intermediary. A lead, local, or a single intermediary must be an organization that is a designated regional intermediary. Any request made under this paragraph is evaluated by CMS in accordance with the criteria contained at § 421.106 of this subpart.

(f) An HHA or hospice not wishing to receive payment from a regional intermediary designated under paragraph (c) or (d) of this section may submit a request to the CMS Regional Office to receive payment through an alternative regional intermediary designated by CMS.

(g) Except as provided in paragraph (h) of this section, any request that an HHA or hospice may make to change from a designated regional intermediary to an alternative designated regional intermediary, in accordance with paragraph (f) of this section, is evaluated by CMS in accordance with the criteria set forth at § 421.106(b) of this subpart and must be filed within the timeframe established at § 421.106(a) of this subpart.

(h) *Exception:* An HHA or a hospice that, as of June 20, 1988 is receiving payment from a designated regional intermediary may, without regard to the limitations contained in § 421.106 of this subpart, continue to receive payment from that intermediary. It may do so even if that intermediary is not the designated regional intermediary or the alternative designated regional intermediary for the particular State in which the HHA or hospice is located.

[53 FR 17944, May 19, 1988]

#### § 421.118 Awarding of experimental contracts.

Notwithstanding the provisions of §§ 421.103 and 421.104, CMS may award a fixed price or performance incentive contract under the experimental authority contained in 42 U.S.C. 1395b-1 for performance of any of the functions specified in § 421.100. Action taken by CMS under this paragraph is not subject to—

(a) The administrative and judicial review which would otherwise be available under § 421.128; or

(b) Performance criteria and performance standards review as provided for in §§ 421.120 and 421.122.

[45 FR 42179, June 23, 1980, as amended at 59 FR 682, Jan. 6, 1994]

#### § 421.120 Performance criteria.

(a) *Application of performance criteria.* As part of the intermediary evaluations authorized by section 1816(f) of the Act, CMS periodically assesses the performance of intermediaries in their Medicare operations using performance criteria. The criteria measure and evaluate intermediary performance of functional responsibilities such as—

(1) Correct coverage and payment determinations;

(2) Responsiveness to beneficiary concerns; and

(3) Proper management of administrative funds.

(b) *Basis for criteria.* CMS will base the performance criteria on—

(1) Nationwide intermediary experience;

(2) Changes in intermediary operations due to fiscal constraints; and

(3) HFCA's objectives in achieving better performance.

(c) *Publication of criteria.* The development and revision of criteria for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, CMS will publish the performance criteria as a notice in the FEDERAL REGISTER.

[48 FR 7178, Feb. 18, 1983]

#### § 421.122 Performance standards.

(a) *Development of standards.* In addition to the performance criteria (§ 421.120), CMS develops detailed performance standards for use in evaluating intermediary performance which may be based on historical performance, application of acceptable statistical measures of variation to nationwide intermediary experience during a base period, or changing program emphases or requirements. These standards are also developed considering intermediary experience and evaluate

#### § 421.124

the specific requirements of each functional responsibility or criterion.

(b) *Factors beyond intermediary's control.* To identify measurable factors that significantly affect an intermediary's performance, but that are not within the intermediary's control, CMS will—

(1) Study the performance of intermediaries during the base period, and

(2) Consider the noncontrollable factors in developing performance standards.

(c) *Publication of standards.* The development and revision of standards for evaluating intermediary performance is a continuing process. Therefore, before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1-September 30, CMS publishes the performance standards as part of the FEDERAL REGISTER notice describing the performance criteria issued under § 421.120(c). CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase "before the beginning of each evaluation period" as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the intermediaries for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

#### § 421.124 Intermediary's failure to perform efficiently and effectively.

(a) Failure by an intermediary to meet, or to demonstrate the capacity to meet, the criteria or standards specified in §§ 421.120 and 421.122 may be grounds for adverse action by the Secretary or by CMS, such as reassignment of providers, offer of a short-term agreement, termination of a contract, or non-renewal of a contract. If an intermediary meets all criteria and standards in its overall performance, but does not meet them with respect to a specific provider or class of providers, CMS may reassign that provider or class of providers to another intermediary in accordance with § 421.114.

(b) In addition, notwithstanding whether an intermediary meets the criteria and standards, if the cost in-

#### 42 CFR Ch. IV (10-1-03 Edition)

curred by the intermediary to meet its contractual requirements exceeds the amount which CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated intermediary, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

#### § 421.126 Termination of agreements.

(a) *Termination by intermediary.* An intermediary may terminate its agreement at any time by—

(1) Giving written notice of its intention to CMS and to the providers it services at least 180 days before its intended termination date; and

(2) Giving public notice of its intention by publishing a statement of the effective date of termination at least 60 days before that date. Publication must be in a newspaper of general circulation in each community served by the intermediary.

(b) *Termination by the Secretary, and right of appeal.* (1) The Secretary may terminate an agreement if—

(i) The intermediary fails to comply with the requirements of this subpart;

(ii) The intermediary fails to meet the criteria or standards specified in §§ 421.120 and 421.122; or

(iii) CMS has reassigned, under § 421.114 or § 421.116, all of the providers assigned to the intermediary.

(2) If the Secretary decides to terminate an agreement, he or she will offer the intermediary an opportunity for a hearing, in accordance with § 421.128.

(3) If the intermediary does not request a hearing, or if the hearing decision affirms the Secretary's decision, the Secretary will provide reasonable notice of the effective date of termination to—

(i) The intermediary;

(ii) The providers served by the intermediary; and

(iii) The general public.

(4) The providers served by the intermediary will be given the opportunity to nominate another intermediary, in accordance with § 421.104.



**§ 421.128 Intermediary's opportunity for hearing and right to judicial review.**

(a) *Basis for appeal.* An intermediary adversely affected by any of the following actions shall be granted an opportunity for a hearing:

(1) Assignment or reassignment of providers to another intermediary.

(2) Designation of a national or regional intermediary to serve a class of providers.

(3) Termination of the agreement.

(b) *Request for hearing.* The intermediary shall file the request with CMS within 20 days from the date on the notice of intended action.

(c) *Hearing procedures.* The hearing officer shall be a representative of the Secretary and not otherwise a party to the initial administrative decision. The intermediary may be represented by counsel and may present evidence and examine witnesses. A complete recording of the proceedings at the hearing will be made and transcribed.

(d) *Judicial review.* An adverse hearing decision concerning action under paragraph (a)(1) or (a)(2) of this section is subject to judicial review in accordance with 5 U.S.C. chapter 7.

(e) As specified in § 421.118, contracts awarded under the experimental authority of CMS are not subject to the provisions of this section.

(f) *Exception.* An intermediary adversely affected by the designation of a regional intermediary or an alternative regional intermediary for HHAs, or an intermediary for hospices, under § 421.117 of this subpart is not entitled to a hearing or judicial review concerning adverse effects caused by the designation of an intermediary.

[45 FR 42179, June 23, 1980, as amended at 47 FR 38540, Sept. 1, 1982; 49 FR 3660, Jan. 30, 1984; 53 FR 17945, May 19, 1988]

**Subpart C—Carriers****§ 421.200 Carrier functions.**

A contract between CMS and a carrier, other than a regional DMEPOS carrier, specifies the functions to be performed by the carrier which must include, but are not necessarily limited to, the following:

(a) *Coverage.* (1) The carrier ensures that payment is made only for services that are:

(i) Furnished to Medicare beneficiaries;

(ii) Covered under Medicare; and

(iii) In accordance with QIO determinations when they are services for which the QIO has assumed review responsibility under its contract with CMS.

(2) The carrier takes appropriate action to reject or adjust the claim if—

(i) The carrier or the QIO determines that the services furnished or proposed to be furnished were not reasonable, not medically necessary, or not furnished in the most appropriate setting;

(ii) The carrier determines that the claim does not properly reflect the kind and amount of services furnished.

(b) *Payment on a cost basis.* If payment is on a cost basis, the carrier must assure that payments are based on reasonable costs, as determined under part 413 of this chapter.

(c) *Payment on a charge basis.* If payment is on a charge basis, under part 405, subpart E of this chapter, the carrier must ensure that—

(1) Charges are reasonable and not higher than the charge for a comparable service furnished under comparable circumstances to the carrier's policy holders and subscribers; and

(2) The payment is based on one of the following—

(i) An itemized bill.

(ii) An assignment under the terms of which the reasonable charge is the full charge for the service, as specified in § 424.55 of this chapter.

(iii) If the beneficiary has died, the procedures set forth in §§ 424.62 and 424.64 of this chapter.

(d) *Fiscal management.* The carrier must receive, disburse, and account for funds in making payments under Medicare.

(e) *Provider audits.* The carrier must audit the records of providers to whom it makes Medicare Part B payments to assure that payments are made properly.

(f) *Utilization patterns.* (1) The carrier must have methods and procedures for identifying utilization patterns that deviate from professionally established norms and bring the deviant patterns

## § 421.201

## 42 CFR Ch. IV (10–1–03 Edition)

to the attention of appropriate professional groups.

(2) The carrier must assist providers and other persons who furnish Medicare Part B services to—

(i) Develop procedures relating to utilization practices;

(ii) Make studies of the effectiveness of those procedures and devise methods to improve them;

(iii) Apply safeguards against unnecessary utilization of services; and

(iv) Develop procedures for utilization review, and establish groups to perform such reviews of providers to whom it makes Medicare Part B payments.

(g) *Information and reports.* The carrier must furnish to CMS any information and reports that CMS requests in order to carry out CMS's responsibilities in the administration of the Medicare program. The carrier must be responsive to requests for information from the public.

(h) *Maintenance and availability of records.* The carrier must maintain and make available to CMS the records necessary for verification of payments and for other related purposes.

(i) *Hearings to Part B beneficiaries.* (1) The carrier must provide an opportunity for a fair hearing if it denies the beneficiary's request for payment, does not act upon the request with reasonable promptness, or pays less than the amount claimed.

(2) The hearing procedures must be in accordance with part 405, subpart H, of this chapter (Review and Hearing Under the Supplementary Medical Insurance Program).

(j) *Other terms and conditions.* The carrier must comply with any other terms and conditions included in its contract.

[45 FR 42183, Jun. 23, 1980; 45 FR 64913, Oct. 1, 1980, as amended at 49 FR 3660, Jan. 30, 1984; 49 FR 9174, Mar. 12, 1984; 51 FR 34833, Sept. 30, 1986; 51 FR 41350, Nov. 14, 1986; 51 FR 43198, Dec. 1, 1986; 52 FR 4499, Feb. 12, 1987; 53 FR 6648, Mar. 2, 1988; 54 FR 4027, Jan. 27, 1989; 57 FR 27307, June 18, 1992]

### § 421.201 Performance criteria and standards.

(a) *Application of performance criteria and standards.* As part of the carrier evaluations mandated by section 1842(b)(2) of the Act, CMS periodically

assesses the performance of carriers in their Medicare operations using performance criteria and standards.

(1) The criteria measure and evaluate carrier performance of functional responsibilities such as—

(i) Accurate and timely payment determinations;

(ii) Responsiveness to beneficiary, physician, and supplier concerns; and

(iii) Proper management of administrative funds.

(2) The standards evaluate the specific requirements of each functional responsibility or criterion.

(b) *Basis for criteria and standards.* CMS bases the performance criteria and standards on—

(1) Nationwide carrier experience;

(2) Changes in carrier operations due to fiscal constraints; and

(3) CMS's objectives in achieving better performance.

(c) *Publication of criteria and standards.* Before the beginning of each evaluation period, which usually coincides with the Federal fiscal year period of October 1–September 30, CMS publishes the performance criteria and standards as a notice in the FEDERAL REGISTER. CMS may not necessarily publish the criteria and standards every year. CMS interprets the statutory phrase “before the beginning of each evaluation period” as allowing publication of the criteria and standards after the Federal fiscal year begins, as long as the evaluation period of the carriers for the new criteria and standards begins after the publication of the notice.

[59 FR 682, Jan. 6, 1994]

### § 421.202 Requirements and conditions.

Before entering into or renewing a carrier contract, CMS determines that the carrier—

(a) Has the capacity to perform its contractual responsibilities effectively and efficiently;

(b) Has the financial responsibility and legal authority necessary to carry out its responsibilities; and

(c) Will be able to meet any other requirements CMS considers pertinent, and, if designated a regional DMEPOS carrier, any special requirements for

regional carriers under § 421.210 of this subpart.

[45 FR 42179, June 23, 1980, as amended at 57 FR 27307, June 18, 1992]

**§ 421.203 Carrier's failure to perform efficiently and effectively.**

(a) Failure by a carrier to meet, or demonstrate the capacity to meet, the criteria and standards specified in § 421.201 may be grounds for adverse action by the Secretary, such as contract termination or non-renewal.

(b) Notwithstanding whether or not a carrier meets the criteria and standards specified in § 421.201, if the cost incurred by the carrier to meet its contractual requirements exceeds the amount that CMS finds to be reasonable and adequate to meet the cost which must be incurred by an efficiently and economically operated carrier, those high costs may also be grounds for adverse action.

[59 FR 682, Jan. 6, 1994]

**§ 421.205 Termination by the Secretary.**

(a) *Cause for termination.* The Secretary may terminate a contract with a carrier at any time if he or she determines that the carrier has failed substantially to carry out any material terms of the contract or has performed its function in a manner inconsistent with the effective and efficient administration of the Medicare Part B program.

(b) *Notice and opportunity for hearing.* Upon notification of the Secretary's intent to terminate the contract, the carrier may request a hearing within 20 days after the date on the notice of intent to terminate.

(c) *Hearing procedures.* The hearing procedures will be those specified in § 421.128(c).

**§ 421.210 Designations of regional carriers to process claims for durable medical equipment, prosthetics, orthotics and supplies.**

(a) *Basis.* This section is based on sections 1834(a) and 1834(h) of the Act which authorize the Secretary to designate one or more carriers by specific regions to process claims for durable medical equipment, prosthetic devices, prosthetics, orthotics and other sup-

plies (DMEPOS). This authority has been delegated to CMS.

(b) *Types of claims.* Claims for the following, except for items incident to a physician's professional service as defined in § 410.26, incident to a physician's service in a rural health clinic as defined in § 405.2413, or bundled into payment to a provider, ambulatory surgical center, or other facility, are processed by the designated carrier for its designated region and not by other carriers—

(1) Durable medical equipment (and related supplies) as defined in section 1861(n) of the Act;

(2) Prosthetic devices (and related supplies) as described in section 1861(s)(8) of the Act, (including intra-ocular lenses and parenteral and enteral nutrients, supplies, and equipment, when furnished under the prosthetic device benefit);

(3) Orthotics and prosthetics (and related supplies) as described in section 1861(s)(9);

(4) Home dialysis supplies and equipment as described in section 1861(s)(2)(F);

(5) Surgical dressings and other devices as described in section 1861(s)(5);

(6) Immunosuppressive drugs as described in section 1861(s)(2)(J); and

(7) Other items or services which are designated by CMS.

(c) *Region designation.* The boundaries of the four regions for processing claims described in paragraph (b) of this section coincide with the boundaries of 1 or more sectors or areas designated for the Common Working File. These four regions contain the following States and territories: Region A: Maine, New Hampshire, Vermont, Massachusetts, Connecticut, Rhode Island, New York, New Jersey, Pennsylvania, and Delaware. Region B: Maryland, the District of Columbia, Virginia, West Virginia, Ohio, Michigan, Indiana, Illinois, Wisconsin and Minnesota. Region C: North Carolina, South Carolina, Kentucky, Tennessee, Georgia, Florida, Alabama, Mississippi, Louisiana, Texas, Arkansas, Oklahoma, New Mexico, Colorado, Puerto Rico and the Virgin Islands. Region D: Alaska, Hawaii, American Samoa, Guam, the Northern Mariana Islands,

## § 421.212

California, Nevada, Arizona, Washington, Oregon, Montana, Idaho, Utah, Wyoming, North Dakota, South Dakota, Nebraska, Kansas, Iowa and Missouri.

(d) *Criteria for designating regional carriers.* CMS designates regional carriers to achieve a greater degree of effectiveness and efficiency in the administration of the Medicare program as measured by—

- (1) Timeliness of claim processing;
- (2) Cost per claim;
- (3) Claim processing quality;
- (4) Experience in claim processing, and in establishing local medical review policy; and
- (5) Other criteria that CMS believes to be pertinent.

(e) *Carrier designation.* (1) Each carrier designated a regional carrier is responsible, using the payment rates applicable for the State of residence of a beneficiary, including a qualified Railroad Retirement beneficiary, for processing claims for items listed in paragraph (b) of this section for beneficiaries whose permanent residence is within the area designated in paragraph (c) of this section. A beneficiary's permanent residence is the address at which he or she intends to spend 6 months or more of the calendar year.

(2) The regional carriers designated to process DMEPOS claims (as defined in paragraph (b) of this section) for all Medicare beneficiaries residing in their respective regions (as designated in paragraph (c) of this section), including those entitled under the Railroad Retirement Act, are the following:

- (i) The Travelers Insurance Company (Region A), which will be processing claims in Pennsylvania.
  - (ii) Associated Insurance Companies, Inc.—AdminaStar (Region B), which will be processing claims in Indiana.
  - (iii) Blue Cross and Blue Shield of South Carolina (doing business as Palmetto Governments Benefits Administrators) (Region C), which will be processing claims in South Carolina.
  - (iv) Connecticut General Life Insurance Co. (a CIGNA Company) (Region D), which will be processing claims in Tennessee.
- (3) Blue Cross and Blue Shield of South Carolina (Palmetto Government

## 42 CFR Ch. IV (10–1–03 Edition)

Benefits Administrators) has been selected to serve as the National Supplier Clearinghouse and the Statistical Analysis DME regional carrier.

(4) The contracts for the four DME regional carriers will be periodically recompeted. The National Supplier Clearinghouse and Statistical Analysis DME regional carrier do not constitute separate contracts, but are contract amendments to one of the DME regional carrier contracts. The National Supplier Clearinghouse and Statistical Analysis DME regional carrier contract amendments will also be periodically recompeted.

(f) *Collecting information of ownership.* Carriers designated as regional claims processors must obtain from each supplier of items listed in paragraph (b) of this section information concerning ownership and control as required by section 1124A of the Act and part 420 of this chapter, and certifications that supplier standards are met as required by part 424 of this chapter.

[57 FR 27307, June 18, 1992, as amended at 58 FR 60796, Nov. 18, 1993]

### § 421.212 Railroad Retirement Board contracts.

In accordance with this subpart C, the Railroad Retirement Board contracts with DMEPOS regional carriers designated by CMS, as set forth in § 421.210(e)(2), for processing claims for Medicare-eligible Railroad Retirement beneficiaries, for the same contract period as the contracts entered into between CMS and the DMEPOS regional carriers.

[58 FR 60797, Nov. 18, 1993]

### § 421.214 Advance payments to suppliers furnishing items or services under Part B.

(a) *Scope and applicability.* This section provides for the following:

(1) Sets forth requirements and procedures for the issuance and recovery of advance payments to suppliers of Part B services and the rights and responsibilities of suppliers under the payment and recovery process.

(2) Does not limit CMS's right to recover unadjusted advance payment balances.

(3) Does not affect suppliers' appeal rights under part 405, subpart H of this

chapter relating to substantive determinations on suppliers' claims.

(4) Does not apply to claims for Part B services furnished by suppliers that have in effect provider agreements under section 1866 of the Act and part 489 of this chapter, and are paid by intermediaries.

(b) *Definition.* As used in this section, *advance payment* means a conditional partial payment made by the carrier in response to a claim that it is unable to process within established time limits.

(c) *When advance payments may be made.* An advance payment may be made if all of the following conditions are met:

(1) The carrier is unable to process the claim timely.

(2) CMS determines that the prompt payment interest provision specified in section 1842(c) of the Act is insufficient to make a claimant whole.

(3) CMS approves, in writing to the carrier, the making of an advance payment by the carrier.

(d) *When advance payments are not made.* Advance payments are not made to any supplier that meets any of the following conditions:

(1) Is delinquent in repaying a Medicare overpayment.

(2) Has been advised of being under active medical review or program integrity investigation.

(3) Has not submitted any claims.

(4) Has not accepted claims' assignments within the most recent 180-day period preceding the system malfunction.

(e) *Requirements for suppliers.* (1) Except as provided for in paragraph (g)(1) of this section, a supplier must request, in writing to the carrier, an advance payment for Part B services it furnished.

(2) A supplier must accept an advance payment as a conditional payment subject to adjustment, recoupment, or both, based on an eventual determination of the actual amount due on the claim and subject to the provisions of this section.

(f) *Requirements for carriers.* (1) A carrier must notify a supplier as soon as it is determined that payment will not be made in a timely manner, and an advance payment option is to be offered to the supplier.

(i) A carrier must calculate an advance payment for a particular claim at no more than 80 percent of the anticipated payment for that claim based upon the historical assigned claims payment data for claims paid the supplier.

(ii) "Historical data" are defined as a representative 90-day assigned claims payment trend within the most recent 180-day experience before the system malfunction.

(iii) Based on this amount and the number of claims pending for the supplier, the carrier must determine and issue advance payments.

(iv) If historical data are not available or if backlogged claims cannot be identified, the carrier must determine and issue advance payments based on some other methodology approved by CMS.

(v) Advance payments can be made no more frequently than once every 2 weeks to a supplier.

(2) Generally, a supplier will not receive advance payments for more assigned claims than were paid, on a daily average, for the 90-day period before the system malfunction.

(3) A carrier must recover an advance payment by applying it against the amount due on the claim on which the advance was made. If the advance payment exceeds the Medicare payment amount, the carrier must apply the unadjusted balance of the advance payment against future Medicare payments due the supplier.

(4) In accordance with CMS instructions, a carrier must maintain a financial system of data in accordance with the Statement of Federal Financial Accounting Standards for tracking each advance payment and its recoupment.

(g) *Requirements for CMS.* (1) In accordance with the provisions of this section, CMS may determine that circumstances warrant the issuance of advance payments to all affected suppliers furnishing Part B services. CMS may waive the requirement in paragraph (e)(1) of this section as part of that determination.

(2) If adjusting Medicare payments fails to recover an advance payment, CMS may authorize the use of any other recoupment method available (for example, lump sum repayment or

an extended repayment schedule) including, upon written notice from the carrier to the supplier, converting any unpaid balances of advance payments to overpayments. Overpayments are recovered in accordance with part 401, subpart F of this chapter concerning claims collection and compromise and part 405, subpart C of this chapter concerning recovery of overpayments.

(h) *Prompt payment interest.* An advance payment is a “payment” under section 1842(c)(2)(C) of the Act for purposes of meeting the time limit for the payment of clean claims, to the extent of the advance payment.

(i) *Notice, review, and appeal rights.* (1) The decision to advance payments and the determination of the amount of any advance payment are committed to CMS’s discretion and are not subject to review or appeal.

(2) The carrier must notify the supplier receiving an advance payment about the amounts advanced and recouped and how any Medicare payment amounts have been adjusted.

(3) The supplier may request an administrative review from the carrier if it believes the carrier’s reconciliation of the amounts advanced and recouped is incorrectly computed. If a review is requested, the carrier must provide a written explanation of the adjustments.

(4) The review and explanation described in paragraph (i)(3) of this section is separate from a supplier’s right to appeal the amount and computation of benefits paid on the claim, as provided at part 405, subpart H of this chapter. The carrier’s reconciliation of amounts advanced and recouped is not an initial determination as defined at §405.803 of this chapter, and any written explanation of a reconciliation is not subject to further administrative review.

[61 FR 49275, Sept. 19, 1996]

## PART 422—MEDICARE+CHOICE PROGRAM

### Subpart A—General Provisions

Sec.

422.1 Basis and scope.

422.2 Definitions.

422.4 Types of M+C plans.

422.6 Application requirements.

422.8 Evaluation and determination procedures.

422.10 Cost-sharing in enrollment-related costs (M+C user fee).

### Subpart B—Eligibility, Election, and Enrollment

422.50 Eligibility to elect an M+C plan.

422.54 Continuation of enrollment.

422.56 Limitations on enrollment in an M+C MSA plan.

422.57 Limited enrollment under M+C RFB plans.

422.60 Election process

422.62 Election of coverage under an M+C plan.

422.64 Information about the M+C program.

422.66 Coordination of enrollment and disenrollment through M+C organizations.

422.68 Effective dates of coverage and change of coverage.

422.74 Disenrollment by the M+C organization.

422.80 Approval of marketing materials and election forms.

### Subpart C—Benefits and Beneficiary Protections

422.100 General requirements.

422.101 Requirements relating to basic benefits.

422.102 Supplemental benefits.

422.103 Benefits under an M+C MSA plan.

422.104 Special rules on supplemental benefits for M+C MSA plans.

422.105 Special rules for point of service option.

422.106 Coordination of benefits with employer or union group health plans and Medicaid.

422.108 Medicare secondary payer (MSP) procedures.

422.109 Effect of national coverage determinations (NCDs) and legislative changes in benefits.

422.110 Discrimination against beneficiaries prohibited.

422.111 Disclosure requirements.

422.112 Access to services.

422.113 Special rules for ambulance services, emergency and urgently needed services, and maintenance and post-stabilization care services.

422.114 Access to services under an M+C private fee-for-service plan.

422.118 Confidentiality and accuracy of enrollee records.

422.128 Information on advance directives.

422.132 Protection against liability and loss of benefits.

422.133 Return to home skilled nursing facility.